Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
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510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K191365

B Applicant

Nova Biomedical Corporation

C Proprietary and Established Names

Stat Profile Prime ES Comp Plus Analyzer System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
JGS	Class II	21 CFR 862.1665 - Sodium Test System	CH - Clinical Chemistry
CEM	Class II	21 CFR 862.1600 - Potassium test system	CH - Clinical Chemistry
CGZ	Class II	21 CFR 862.1170 - Chloride test system	CH - Clinical Chemistry
JJE	Class I	21 CFR 862.2160 - Discrete photometric chemistry analyzer for clinical use	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New Device

B Measurand:

Sodium, Potassium and Chloride

C Type of Test:

Quantitative, potentiometric, ion selective electrode technology.

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) for Use:

The Stat Profile Prime ES Comp Plus Analyzer System is intended for in vitro diagnostic use by health care professionals in clinical laboratory settings for the quantitative determination of sodium, potassium, and chloride in heparinized venous whole blood, plasma and serum. Sodium measurement is used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, or diseases involving electrolyte imbalance.

Potassium measurement is used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high potassium levels.

Chloride measurement is used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only
Not for Point-of-care use

D Special Instrument Requirements:

Stat Profile Prime ES Comp Plus Analyzer System

IV Device/System Characteristics:

A Device Description:

The Stat Profile Prime ES Comp Plus Analyzer System is designed to be used in a clinical laboratory setting. The analyzer consists of, sensor cartridges, calibrator packs, ampuled quality control materials (external controls) and thermal paper for an onboard printer. Specimens are identified by scanning a barcode or by manually entering the information via the touchscreen.

The Stat Profile Prime ES Comp Plus Analyzer has slots to accommodate two sensor cartridges (primary and auxiliary). The analyzer will determine the configuration of the system by detecting which sensor cards are installed.

B Principle of Operation:

The sodium, potassium, and chloride parameters are measured by an ion-selective electrode (ISE) that selectively measures the activity of ionic species. When the ISE comes in contact with a sample, a potential is developed. This potential is proportional to the logarithm of the ionic activity and is measured versus a reference electrode, as described by the Nernst equation.

C Instrument Description Information:

Modes of Operation	Yes	No
Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?	☒	☐
Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?	☒	☐
Software		
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types.	☒	☐

1. Instrument Name:

   Stat Profile Prime ES Comp Plus Analyzer System

2. Specimen Identification:

   Specimen may be identified by scanning a barcode or by manually entering the information via the touchscreen.

3. Specimen Sampling and Handling:

   Lithium heparinized venous whole blood from syringes and open blood collection tubes or containers can be aspirated by positioning the sample over a probe . Plasma and serum samples from open containers can be sampled over a probe or using the tray mode.

4. Calibration:

   The Analyzer has an automated calibrator which is used to perform a 2-point calibration 30 minutes after being powered on and regularly thereafter to maintain optimal Sensor Card and air detector performance. Then a 1-point calibration is performed at regular intervals to monitor the Sensor Card's performance between each 2-point calibration.

5. Quality Control:

The sponsor recommends that controls be assayed daily and/or after performing system maintenance. The frequency of controls should correspond to laboratory guidelines and follow federal, state and local guidelines.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Nova Stat Profile pHOx Ultra Blood Gas Analyzer System

B Predicate 510(k) Number(s):

k110648

C Comparison with Predicate(s):

Device & Predicate Device(s):	K191365	K110648
Device Trade Name	Stat Profile Prime ES Comp Plus Analyzer System	Nova Stat Profile pHOx Ultra Analyzer System
General Device Characteristic Similarities		
Intended Use/Indications for Use	For the quantitative determination of sodium, potassium, and chloride, in heparinized venous whole blood, plasma and serum.	Same
Measuring range – Na	80-200 mmol/L	Same
Measuring range – K	1.0-20.0 mmol/L	Same
Measuring range – CL	50-200 mmol/L	Same
Measuring Principle	Ion selective electrode	Same
General Device Characteristic Differences		
Sample Volume	100 µL	60-210 µL dependent on selected test panel
Touch Screen	5.7" VGA full color display with LED backlight and integrated touch panel	12.1" LCD, 1024x768 pixel, Resistive Touch
Bar Code Scanner	Internal Integrated 1D/2D	External (optional) 1D

VI Standards/Guidance Documents Referenced:

- CLSI EP05-A3: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Third Edition.
- CSLI EP06-A Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline.
- CLSI EP07-A3 Interference Testing in Clinical Chemistry; Approved Guideline - Third Edition.
- CLSI EP17-A Protocols fort Determination of Limits of Detection and Limits of Quantitation; Approved Guideline.
- EP25-A: Evaluation of In Vitro Diagnostic Reagents; Approved Guideline.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Within-Run Precision:
The study was performed following the CLSI EP05-A3 guideline. Within-Run and between-analyzer precision study were performed using two levels of quality control materials, whole blood, serum and lithium heparin plasma samples, on three Stat Profile Prime ES Comp Plus Analyzers. Each sample was tested in one run in replicates of 20 on each of the three analyzers. The results of one representative analyzer are summarized in the table below:

Within-run precision using External Quality samples:

Parameter	n=20	Control Level 1	Control Level 2
Sodium (mmol/L)	Mean SD %CV	147.5 0.2 0.2	118.9 0.5 0.4
Potassium (mmol/L)	Mean SD %CV	3.67 0.0 0.1	6.34 0.02 0.3
Chloride(mmol/L)	Mean SD %CV	107.0 0.3 0.3	86.4 0.5 0.6

Within-run precision using whole blood samples:

Sodium (mmol/L) (n=20)			
Sample	Mean	SD	%CV
Sample 1	120.7	0.1	0.1
Sample 2	146.8	0.3	0.2
Sample 3	169.1	0.3	0.2

Potassium (mmol/L) (n=20)			
Sample	Mean	SD	%CV
Sample 1	2.39	0.01	0.2
Sample 2	4.07	0.02	0.6
Sample 3	8.23	0.03	0.4

Chloride (mmol/L) (n=20)			
Sample	Mean	SD	%CV
Sample 1	74.9	0.2	0.2
Sample 2	106.5	0.2	0.2
Sample 3	158.8	0.6	0.4

Within-run precision using lithium heparin plasma samples

Sodium (mmol/L) (n=20)			
Sample	Mean	SD	%CV
Sample 1	122.7	0.2	0.2
Sample 2	142.6	0.2	0.1
Sample 3	160.8	0.1	0.1

Potassium (mmol/L) (n=20)			
Sample	Mean	SD	%CV
Sample 1	2.65	0.01	0.5
Sample 2	4.24	0.01	0.2
Sample 3	6.62	0.00	0.1

Chloride (mmol/L) (n=20)			
Sample	Mean	SD	%CV
Sample 1	75.7	0.4	0.5
Sample 2	107.9	0.1	0.1
Sample 3	151.1	0.1	0.1

Within-run precision using serum samples

Sodium (mmol/L) (n=20)			
Sample	Mean	SD	%CV
Sample 1	120.1	0.2	0.2
Sample 2	145.7	0.2	0.1
Sample 3	164.8	0.5	0.3

Potassium (mmol/L) (n=20)			
Sample	Mean	SD	%CV
Sample 1	2.44	0.02	0.8
Sample 2	4.61	0.01	0.1
Sample 3	6.86	0.05	0.8

Chloride (mmol/L) (n=20)			
Sample	Mean	SD	%CV
Sample 1	74.6	0.3	0.4
Sample 2	110.4	0.2	0.2
Sample 3	146.3	0.5	0.3

Run-to run precision:

Run-to-run precision was assessed by analyzing QC samples, each sample was tested in duplicate per run, 2 runs per day, using 3 analyzers over 20 days. The summary results for the three analyte test systems are shown below:

Run-to run precision using External QC samples:

Sodium						
Sample	Pooled mean	N	Within run		Total imprecision	
			SD	%CV	SD	%CV
QC level 1	146.9	240	0.4	0.3	0.7	0.5
QC level 2	119.8	240	0.3	0.3	0.4	0.3

Potassium						
Sample	Pooled mean	N	Within run		Total imprecision	
			SD	%CV	SD	%CV
QC level 1	3.62	240	0.01	0.3	0.03	0.8
QC level 2	6.27	240	0.01	0.2	0.03	0.5

Chloride						
Sample	Pooled mean	N	Within run		Total imprecision	
			SD	%CV	SD	%CV
QC level 1	106.3	240	0.4	0.4	0.6	0.6
QC level 2	85.9	240	0.4	0.5	0.8	0.9

Run-to-run imprecision using whole blood, serum and plasma samples:

To assess run-to-run precision whole blood, lithium heparin plasma and serum samples, triplicate analysis was performed using each of the three sample matrices in ten separate runs on three analyzers for a total of 30 measurements. The systems were recalibrated before each triplicate run. Samples were analyzed on three analyzers. The results from one representative analyzer are summarized in the tables below:

Precision results for Sodium, Potassium and Chloride Matrix: whole blood:

Parameter	N=30	Sample 1	Sample 2	Sample 3
Sodium (mmol/L)	Mean	122.0	144.7	162.9
	SD	0.3	0.2	0.3
	%CV	0.3	0.1	0.2
Potassium (mmol/L)	Mean	2.54	3.58	6.81
	SD	0.04	0.01	0.04
	%CV	1.5	0.4	0.6

Parameter	N=30	Sample 1	Sample 2	Sample 3
Chloride (mmol/L)	Mean	77.5	106.9	148.5
	SD	0.6	0.1	0.3
	%CV	0.8	0.1	0.2

Precision results for Sodium, Potassium and Chloride Matrix: Plasma

Parameter	N=30	Sample 1	Sample 2	Sample 3
Sodium (mmol/L)	Mean	119.3	143.9	162.5
	SD	0.5	0.2	0.6
	%CV	0.4	0.2	0.4
Potassium (mmol/L)	Mean	2.63	4.03	6.43
	SD	0.02	0.01	0.04
	%CV	0.8	0.2	0.7
Chloride (mmol/L)	Mean	66.4	106.9	153.4
	SD	05	0.2	0.5
	%CV	0.7	0.2	0.3

Precision results for Sodium, Potassium and Chloride Matrix: Serum

Parameter	N=30	Sample 1	Sample 2	Sample 3
Sodium (mmol/L)	Mean	119.5	140.5	162.3
	SD	0.4	0.4	0.3
	%CV	0.3	0.3	0.2
Potassium (mmol/L)	Mean	2.62	4.35	6.86
	SD	0.03	0.01	0.01
	%CV	1.2	0.3	0.2
Chloride (mmol/L)	Mean	64.4	105.0	158.0
	SD	0.5	0.3	0.5
	%CV	0.8	0.3	0.3

2. Linearity:

The linearity studies were performed following the CLSI EP6-A guideline. The studies were performed on three analyzers using lithium heparinized venous whole blood, plasma and serum . Low and high concentration pools were mixed and serial dilution samples (N=10 or 11) were prepared and tested in triplicate. The results from each candidate analyzer for each parameter were compared to expected values. All three analyzers yielded similar results. The results of the least squares linear regression analysis from one representative analyzer are summarized below:

Lithium heparin whole blood:

Analyte	Claimed Measuring Range (mmol/L)	Sample Range Tested (mmol/L)	Slope	Intercept	r
Sodium	80 - 200	73.4 - 213.9	0.9975	0.8170	0.9998
Potassium	1.0 - 20.0	0.86 - 24.08	1.0079	-0.0642	0.9997
Chloride	50 - 200	48.8 - 203.7	1.0027	-0.7042	0.9999

Lithium heparin plasma:

Analyte	Claimed Measuring Range (mmol/L)	Sample Range Tested (mmol/L)	Slope	Intercept	r
Sodium	80 - 200	73.9 - 207.3	1.0118	-1.6007	0.9999
Potassium	1.0 - 20.0	0.95 - 22.23	1.0064	-0.1220	0.9999
Chloride	50 - 200	45.9 - 206.9	1.0018	0.0538	0.9999

Serum:

Analyte	Claimed Measuring Range (mmol/L)	Sample Range Tested (mmol/L)	Slope	Intercept	r
Sodium	80 - 200	78.6 - 207.8	0.9914	0.3424	0.9998
Potassium	1.0 - 20.0	0.92 - 21.03	0.9930	-0.0625	0.9989
Chloride	50 - 200	49.5 - 202.7	0.9809	1.6611	0.9999

The linear regression results support the claimed measuring ranges, as summarized in the tables above.

3. Analytical Specificity/Interference:

Interference studies were performed according to CLSI EP07-A3 guideline. The sponsor collected serum sample and plasma from donors. Samples were divided to create two separate pools one for control and the other for test samples. The potential interferents were tested at two analyte concentrations. If interference was identified, then a dose response was performed to determine the lowest concentration where the interfering substance may alter the results. For all analytes, the sponsor defined interference as > ± 10% bias from the test results when compared to the control sample. The sponsor determined the following substances did not cause interference at the concentrations listed below:

Sodium:

Interferent	Highest concentration tested that did not cause significant interference
Acetoacetate	2 mmol/L
Acetylsalicylic Acid	3.62 mmol/L
Ammonium Chloride	107µmol/L
Ascorbic Acid	50 mg/dL
Benzalkonium Chloride	10 mg/dL
Bilirubin (Conjugate)	342 µmol/L
Calcium Chloride	2 mmol/L
Dobutamine	2 mg/dL
Hemoglobin	2 g/dL
Ibuprofen	2.4 mmol/L
Intralipid	4000 mg/dL
Lithium Lactate	6.6 mmol/L
Magnesium Chloride	15 mmol/L
Potassium Chloride	5 mmol/L
Salicylic Acid	4.34 mmol/L

Interferent	Highest concentration tested that did not cause significant interference
Sodium Thiocyanate	6.8 mmol/L
Zinc Chloride	1.3 mg/L

Potassium:

Interferent	Highest concentration tested that did not cause significant interference
Acetoacetate	2 mmol/L
Acetylsalicylic Acid	3.62 mmol/L
Ammonium Chloride	107µmol/L
Ascorbic Acid	50 mg/dL
Benzalkonium Chloride	10 mg/dL
Bilirubin (Conjugate)	342 µmol/L
Calcium Chloride	2 mmol/L
Dobutamine	2 mg/dL
Hemoglobin	2 g/dL
Ibuprofen	2.4 mmol/L
Intralipid	4000 mg/dL
Lithium Lactate	6.6 mmol/L
Magnesium Chloride	15 mmol/L
Salicylic Acid	4.34 mmol/L
Sodium Bromide	37.5 mmol/L
Sodium Chloride	10 mmol/L
Sodium Citrate	12 mmol/L
Sodium Iodide	2.99 mmol/L
Sodium Oxalate	500 mg/dL
Sodium Perchlorate	1 mmol/L
Sodium Thiocyanate	6.8 mmol/L
Zinc Chloride	1.3 mg/dL

Chloride:

Interferent	Highest concentration tested that did not cause significant interference
Acetoacetate	2 mmol/L
Acetylsalicylic Acid	3.62 mmol/L
Ammonium Chloride	107µmol/L
Ascorbic Acid	50 mg/dL
Benzalkonium Chloride	10 mg/dL
Bilirubin (Conjugate)	342 µmol/L
Dobutamine	2 mg/dL
Hemoglobin	2 g/dL
Ibuprofen	2.4 mmol/L
Intralipid	4000 mg/dL
Lithium Lactate	6.6 mmol/L
Salicylic Acid	4.34 mmol/L
Sodium Citrate	12 mmol/L

Interferent	Highest concentration tested that did not cause significant interference
Sodium Oxalate	500 mg/dL
Sodium Perchlorate	1 mmol/L

The sponsor has listed the following interfering substances as causing clinically significant effects on test results in whole blood, serum and plasma samples in the labeling:

Parameter	Interferent	Interferent Observed at Concentrations Above:
Chloride	Sodium Bromide	2.3 mmol/L
	Sodium Iodide	1.5 mmol/L
	Sodium Thiocyanate	1.7 mmol/L

4. Assay Reportable Range:

Reportable ranges for venous whole blood, plasma and serum:

Analyte	Claimed Measuring Range (mmol/L)
Sodium	80 - 200
Potassium	1.0 - 20.0
Chloride	50 - 200

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

The sodium and chloride standards and reagents are traceable to NIST SRM 919a.
The potassium standards and reagents are traceable to NIST SRM 918a.

6. Detection Limit:

The performance at the lower end of the measuring range for sodium, potassium, and chloride is supported by the linearity studies (see section VII.A.2 above).

7. Assay Cut-Off:

Not applicable.

8. Accuracy (Instrument):

Not applicable.

9. Carry-Over:

No applicable

B Comparison Studies:

1. Method Comparison with Predicate Device:

A method comparison study was performed by testing a minimum of one hundred and fifty lithium heparin whole blood samples and a minimum of one hundred samples for serum and lithium heparin plasma on one Stat Profile Prime ES Comp Plus Analyzer (candidate device) and two Stat Profile pHOx Ultra Analyzers (predicate device) for each parameter. In order to cover the extreme ends of the claimed measuring range a limited number of specimens were spiked or diluted . The singlet result from each test analyzer was compared to the average of the results from the comparative method.

The linear regression analyses for the three electrolytes are summarized below:

Lithium heparin whole blood:

Analyte	Slope	Intercept	r^2	N	Range tested (mmol/L)
Sodium	1.0093	-1.2315	0.9951	191	80.2-199.7
Potassium	0.9988	0.0240	0.9995	189	1.70-18.78
Chloride	1.0056	0.4426	0.9958	191	59.1-193.2

Lithium heparin plasma:

Analyte	Slope	Intercept	r^2	N	Range tested (mmol/L)
Sodium	0.9931	1.5744	0.9982	122	83.7-192.0
Potassium	1.0057	0.0177	0.9997	121	1.24-19. 53
Chloride	1.0034	1.4280	0.9977	121	55.6-193.6

Serum:

Analyte	Slope	Intercept	r^2	N	Range tested (mmol/L)
Sodium	1.0029	-0.4950	0.9979	115	84.4-194.8
Potassium	1.0090	-0.0050	0.9999	115	1.01-19.19
Chloride	1.0065	0.2906	0.9989	115	56.4 – 190.6

2. Matrix Comparison:

Not applicable. The performance of each test system with lithium heparin venous whole blood, lithium heparin plasma and serum was evaluated per the studies described in sections VII.A 1 to 5 and VII.B.1. Please see the performance studies above.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Reference range for sodium, potassium and chloride are cited form literature:
Sodium: 136-146 mmol/L
Potassium: 3.5-5.1 mmol/L
Chloride: 98-106 mmol/L

Reference:
Burtis, Carl A. and Ashwood, Edward R., ed. 1994. Tietz Textbook of Clinical Chemistry. Philadelphia, PA: W. B. Saunders Co.

F Other Supportive Instrument Performance Characteristics Data:

Not applicable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.